

ORIGINAL

TSCA NON-CONFIDENTIAL BUSINESS INFORMATION

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COMMENTS:

DOES NOT CONTAIN CBI



April 30, 2013

Via Overnight Courier

TSCA Confidential Business Information Center (7407M)
EPA East – Room 6428
US Environmental Protection Agency
1201 Constitution Ave, NW
Washington, DC 20004-3302
Attention: TSCA Section 8(e) Coordinator



Draft Final Report of a Repeated Dose 28 Day Oral Toxicity Study with m-(2,3-epoxypropoxy)-N,N-bis(2,3-epoxypropyl) aniline, CAS# 71604-74-5.

Dear Sir or Madam:

The European office of Huntsman Advanced Materials (Huntsman) has received a draft final report from a Repeated Dose 28 Day Oral Toxicity Study with m-(2,3-epoxypropoxy)-N,N-bis(2,3-epoxypropyl)aniline, CAS# 71604-74-5. This study was conducted using a standard OECD 407 protocol by WIL Research Europe B.V. in the Netherlands. The results of this repeated dose study have established a No Adverse Effect Level (NOAEL) at 50 mg/kg/day, based on observed atrophy of female reproductive organs at the next highest dose level, 150 mg/kg/day.

Huntsman is submitting this information pursuant to Section 8(e) of the Toxic Substances Control Act (TSCA). Huntsman has not made a determination as to whether a significant risk of injury to human health or the environment is actually presented by these findings.

Study Design:

The test substance was administered, by gavage, to groups of 5 male and 5 female Wistar rats over 28 consecutive days. Dose levels used in this study, formulated in propylene glycol, were 0, 50, 150, and 450 mg/kg/day, with the untreated control group receiving only propylene glycol. The following study parameters were evaluated: daily clinical signs; functional observation battery at study week 4, body weights and food consumption determined weekly; clinical pathology and macroscopic evaluation at study termination, and organ weights and histopathology evaluations on specified tissues.

Study Findings:

- No mortality occurred during this study. However, a poor health status was noted for all animals at the highest dose level of 450 mg/kg/day. Although the functional observation battery (FOB) revealed no effects on hearing, pupil reflex, righting reflex and grip

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strength, the motor activity measurement showed lower activity (total movements and ambulations) at 450 mg/kg/day.

- Animals administered 450 mg/kg/day showed lower body weight gains and reduced body weights compared to control animals. As a result of the poor health status of the animals at 450 mg/kg/day, changes were observed in hematology, clinical biochemistry, organ weights and histopathology. These findings are considered to be a secondary effect unrelated to any specific systemic toxicity of the test substance.
- Atrophy of the uterus, cervix and vagina were observed at 150 mg/kg/day accompanied by the macroscopically visible reduced size of ovaries and uterus at 450 mg/kg/day. In males at 450 mg/kg/day, the prostate gland was considered to be small but with normal histology. At this level, the contents in the seminal vesicles and coagulating glands were considered to be reduced. A lower absolute and/or relative prostate and seminal vesicle weight was noted at the lowest dose level of 50 mg/kg/day, but these observations were not supported by any histological findings, and are not considered to be toxicologically relevant.
- The effects on liver and kidney were noted at 450 mg/kg/day: centrilobular hypertrophy in the liver, discoloration of kidney and adrenals and enlarged adrenal glands in females, with microscopically observed vacuolization of the zona fasciculata in the adrenal glands.
- Effects were observed in the gastrointestinal tract and associated lymphatic system, but these effects are considered to be secondary findings related to the physical properties of the test material and not due to any specific systemic toxicity of the test substance.

Study Conclusion:

Based on the results of this study, the No Observed Adverse Effect Level (NOAEL) for Wistar rats exposed to 2-Propanol, 1-[bis[3-(dimethylamino)propyl]amino]- over 28 consecutive days is considered to be 50 mg/kg/day, based on atrophy of the female reproductive organs observed at 150 mg/kg/day.

As always, if I can provide any additional information on the above study, please call me at (281) 719-3017, or contact me via e-mail at: Ray_Papciak@Huntsman.com.

Regards,

A handwritten signature in black ink, appearing to read 'Ray Papciak', with a long horizontal flourish extending to the right.

Raymond J. Papciak
Manager, Product Safety

From: (281) 719-3028
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Huntsman Corporation
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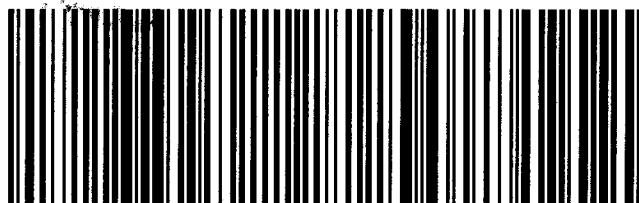
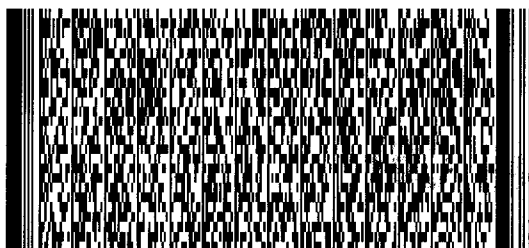
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